K083597

510(k) Summary (Revised 6/7/10)

Submitter: SonoWand AS
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Submission Date: December 3, 2008

Device Name and Classification: SonoWand® Invite, Class II
21 CFR 882.4560, 892.1550
Product Code HAW, IYN

Equivalent Device Identification: BrainLab Vector Vision (K023651), GE Vivid-I (K061525), Seimens Sequoia™ Plus (K072365)

Device Description:
Invite is an integrated neuronavigation system with intraoperative imaging capabilities. The main components of the system are a navigation computer running the Invite software application, an ultrasound scanner and a tracking system in a single rack of equipment.

Invite can be used as a conventional neuronavigation system based on preoperative MR or CT-images, or as a stand-alone ultrasound scanner for real-time 2D imaging. It can also be used as a combined system where high-quality 3D ultrasound data can be transferred to the navigation system for direct navigation. Thus, the surgeon can navigate not only on a preoperative 3D map (MR or CT), but also on an intraoperative 3D ultrasound map which is only a few seconds old. The acquisition time is less than one minute, which means that the surgeon can typically update the navigation map 5-10 times during the surgery. The problem with brain shift is therefore practically eliminated.

The system is contained on a trolley with lockable wheels. This trolley contains power supply, power restrictor, on/off main switch, network and USB ports, an industrial standard PC (navigation computer), the ultrasound unit (GE Vivid-i), probe interface, wiring and cabling. Attached to the trolley is a steel tube column which supports two pendant arms. One of these arms supports an infrared camera (NDI Polaris Spectra). The other arm supports a touch screen, which is the primary user interface.

Invite has two functions. It supports the surgeon by showing the position of tools or pointers relative to MR, CT or Ultrasound images (which will normally show features such as brain

tumors). It also makes it possible for the surgeon to acquire ultrasound images during operation which can be compared with other images (such as MR or CT) and can be used for supporting the surgeon by showing the position of tools and pointers. The control is primarily by a graphical touch screen (which can be draped). The secondary control is by a footswitch.

Data sets (preoperative MR/CT and intraoperative 3D ultrasound) can be used for planning the surgery as well as to navigate in the brain. As the surgery progresses, the accuracy and value of the preoperative images will normally decrease, while ultrasound images will maintain a more precise representation of the true anatomy if these images are updated regularly.

Digital snapshots of the screen can easily be stored during surgery for documentation purposes. It is also possible to review the data sets and to store images after surgery.

Intended Use:

The Sonowand is intended for use as a tool to aid intraoperative ultrasound imaging and image guided surgery during neurosurgery. The Sonowand is intended for use as a standard neuronavigation system. The Sonowand is intended for use as a stand-alone ultrasound scanner.

Comparison Table:

Element of Comparison	Subject Device	Predicate Device	Predicate Device	Predicate Device	Comments
		K023651	K061525	K072365	
	SonoWand Invite	BrainLab Vector Vision	GE Vivid-I	Siemens Sequoia™ Plus system	
Common Name	Intraoperative 3D ultrasound i maging system with navigation for neurosurgery	Image guided surgery system, CAS /Stereotaxy instrument	Diagnostic ultrasound system	Diagnostic ultrasound system	
Intended use	Intended for use as a tool to aid intraoperative ultrasound imaging and image guided surgery during neurosurgery. The Invite is intended for use as a standard neuronavigatio n system. The Invite is intended for use as a stand-alone ultrasound scanner.	The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, CTA, X-ray, MR, MRA and ultrasound based model of the anatomy.	Intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ; Neonatal Cephalic; Adult Cephalic; Cardiac; Peripheral vascular; Musculoskelet al Conventional and Superficial; Urology; Transesophaga l, Transrectal,	Intended for the following applications: Cardiac, neonatal cardiac, pediatric, transesophagea l, adult cephalic, peripheral vessel, intraoperative neurological, musculoskelet al conventional and musculoskelet al superficial applications.	The intended use of the Invite as a navigation tool is the same as for the Vector Vison. The Invite intended use as an ultrasound evaluation tool is the same as for the GE Vivid-i, but limited to the neurological system. The intended use of the Siemens system includes intraoperative neurological.

Element of Comparison	Subject Device	Predicate Device	Predicate Device	Predicate Device	Comments
Types of Procedures	Medical conditions where stereotactic surgery can be appropriate. Identification is relative to MR or CT images and/or to intraoperative ultrasound images. Ultrasound images can be compared with the MR and/or CT images	Cranial procedures Cranial biopsies Tumor resections Caniotomies/ craniectomies Skull base procedures Thalamotomies ENT procedures	Transvaginal, intraoperative		The procedures are the same as to those used for Vector Vision and GE Vivid-i. Invite aids the surgeon, but does not make any decisions or in any way controls the operation.
Major Components	Ultrasound scanner Navigation computer Tracking system (passive marker system) Ultrasound probe Trolley Appendant support system	Freehand probe Navigation computer Passive marker system	Ultrasound scanner Ultrasound probe		The Ultrasound scanner used in Invite is the GE Vivid-i scanner. The tracking system is similar to that used in Vector Vision. The Invite system with its computer, trolley and appendant support is tested by Nemko.
Power Requirements	5A/230V or 10A/110V (Total power demand	Unknown	1.1A/240V to 2.3A/100V		The electric power system is tested by Nemko

Element of Comparison	Subject Device	Predicate Device	Predicate Device	Predicate Device	Comments
	including built in Vivid-i)				
Accessories	GE 12L-RS linear array probe, phased array probe, various disposables		Multiple probes, including the 12L-RS linear array probe.		Invite uses the same probes used for Vivid-i

Conclusion:

The SonoWand Invite is substantially equivalent to the predicate devices regarding intended use, function and technology. The Invite simply combines the functions of the predicate devices into one system.

Intended Use:
The intended use of Invite as a navigation tool is equivalent to the Vector Vision and to the Seimens system incorporating use in the neurological system. The Invite is equivalent to the GE Vivid-I regarding use as an ultrasound evaluation tool.

Function/Technology:
The procedures used with Invite are the same as those used for Vector Vision and Vivid-i. The Invite performs the same type of neuronavigation as the Vector Vision using a similar passive marker system and navigation computer.
The ultrasound scanner and probes are the same as those used with the Vivid-i. Slight modifications were made to the Vivid-i software to enable integration into the Invite software application. These changes do not affect the safe operation of the Vivid-I components confirmed by appropriate ultrasound output testing according to accepted international standards.

Summary of Testing:

The SonoWand Invite system has been verified and validated according to specification requirements. The system has been also been tested to and complies with all applicable EMC/EMI standards. Applicable testing of the ultrasound components has been performed. Results of the tests performed show the SonoWand Invite is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SonoWand AS
% C. G. Bundy Associates, Inc.
Ms. Constance G. Bundy
435 Rice Creek Terrace
Fridley, Minnesota 55432

Re: K083597
Trade/Device Name: SONOWand® Invite
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW, IYN
Dated: August 24, 2009
Received: August 27, 2009

SEP 2 5 2009

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SONOWAND AS
Trondheim, Norway

Indications for Use

510(k) Number (if known): K083597

Device Name: SonoWand® Invite

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The Sonowand is intended for use as a tool to aid intraoperative ultrasound imaging and image guided surgery during neurosurgery. The Sonowand is intended for use as a standard neuronavigation system. The Sonowand is intended for use as a stand-alone ultrasound scanner.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler for MCM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083597